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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,721	04/27/2005	Tomoya Takahashi	00005.001260	8744

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,721	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/27/2005 and 02/05/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *13 and 15-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 15-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 02/05/2008 wherein claims 1-12 and 14 are cancelled, claim 13 is amended and claims 15-29 are newly added.

2. Claims 13 and 15-29 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments/Amendments

3. Applicants arguments filed February 02, 2008 regarding the rejection of claims 1-14 made by the Examiner under 35 USC 112, first paragraph have been fully considered and are found persuasive. This rejection is hereby withdrawn.

4. Applicants arguments filed February 02, 2008 regarding the rejection of claims 14 made by the Examiner under 35 USC 112, second paragraph have been fully considered and are found persuasive. This rejection is hereby withdrawn.

5. Applicants arguments filed February 02, 2008 regarding the rejection of claims 1-12 made by the Examiner under 35 USC 102(a) have been fully considered and are found persuasive. This rejection is hereby withdrawn.

6. Applicants arguments filed February 02, 2008 regarding the rejection of claims 1-12 made by the Examiner under 35 USC 103(a) have been fully considered and are found persuasive. This rejection is hereby withdrawn.

Applicants Invention

7. Applicants are claiming a method of treating atopic dermatitis by orally administering or ingesting an effective amount of hydroxyproline of N-acylted derivative of hydroxyproline wherein the N-acyl group consists of 1-6 carbons. The preparation comprises from 5 to 50% by weight hydroxyproline or N-acylated derivative of hydroxyproline.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 13 and 15-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (EP 1304323; of record, see IDS) in view of Coirre et al. (US 3932638; of record) and Takagi et al. (US 3988466).**

10. Kobayashi et al. ('Kobayashi) is drawn to epidermal ceramide synthesis accelerators and agents for improving atopic dermatitis which employs the active ingredients hydroxyproline or an N-acyl derivative hydroxyproline, or a salt thereof (see abstract). It is disclosed that the hydroxyproline or the N-acyl hydroxyproline derivative is present in the medicament at a weight percentage of 0.1 to 10% from once to several times per day (see page 6, lines 52-55; see instant claims 15-17). It is taught that the N-acyl derivatives include an acyl group having 1 to 24 carbons, more preferably 1 to 12 carbons and most perferably 1 to 6 carbons. Specific examples

include formyl, acetyl, butyryl, and decanoyl groups (see page 4, lines 8-12; see instant claims 19-23). The compounds are delivered in a form of a medicament (see page 5, lines 13-15).

11. Kobayashi fails to specifically teach the hydroxyproline and the N-acylated hydroxyproline derivative as being orally administered.

12. Coirre et al. ('Coirre) is drawn to using derivatives of L-hydroxyproline for the treatment of inflammation and wound healing (see abstract). An exemplified derivative is N-acetyl-L-hydroxyproline (see column 1, lines 55-60 and column 2, lines 57-58) which is taught to be useful for treating conditions affecting wounds by accelerating protein synthesis to stimulate the healing process (see column 1, lines 40-45). It is disclosed that N-acetyl-L-hydroxyproline can be delivered orally in a variety of forms including tablets and capsules (see column 9, lines 35-40; see instant claims 13 and 18). A patient may be administered a therapeutically effective amount of the compound from about 300 to 900 mg/day (see column 9, lines 60-62; see instant claims 27-29).

13. Takagi et al. ('Takagi) is drawn to the prevention of gastric lesions through the administration of amino acids (See abstract). It is taught the L-hydroxyproline is suitable for oral administration in an amount from 1g to 10g/dose (see claims 1 and 3; see instant claims 13 and 18).

14. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Kobayshi, Coirre and Takagi with a reasonable expectation for success in arriving at a method for treating atopic dermatitis by orally administering hydroxyproline or N-acylated hydroxyproline derivative. The significance of Kobayshi is that it teaches that hydroxyproline and N-acylated hydroxyproline derivatives such

as N-acetyl-hydroxyproline and N-butyryl-hydroxyproline are useful accelerating ceramide synthesis thereby reducing the unpleasant effects of atopic dermatitis. Kobayashi fails to teach that hydroxyproline and N-acylated derivatives thereof as being suitable for oral administration. Coirre teaches that hydroxyproline derivatives such as N-acetyl-hydroxyproline are suitable for oral administration. Further, Coirre teaches that a patient may be administered a therapeutically effective amount of the compound from about 300 to 900 mg/day. Takagi teaches that hydroxyproline is suitable for oral administration. With respect to the recited weight because it would be obvious to one of ordinary skill in the art to combine the references and adjust the relative amounts of ingredients with the goal of arriving at a medicament with the greatest therapeutic efficacy. When the general conditions are taught by the prior art, it is not inventive to determine optimum weight percentages or dosage schedules. Therefore, the instant claims are prima facie obvious to one ordinarily skilled in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle Purdy whose telephone number is (571)270-3504. The examiner can normally be reached on M-R 8AM-6PM.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 5712728373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kyle Purdy/
Examiner, Art Unit 1611
February 27, 2008

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615